REMARKS

Claims 1-7, 9, 11, 13-18, and 24-42 have been withdrawn without prejudice or disclaimer. The Examiner has allowed claims 50, 51, and 55. Claims 8, 10, 12, 19-23, and 43-55 are pending and considered. Applicants propose to amend claims 8, 10, 12, 19, 20, 22, 45-49, and 53-54 as follows.

Claims 8, 10, 12, 45-49, and 54 have been amended to recite, "at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1." Support for these amendments can be found in original claims 10, 12, 45-49, and 54, and in the specification, for example, at page 43, lines 12-22.

Claims 8, 10, 46, and 47 have been amended to recite, "at least about 95 percent identical." Support for these amendments can be found in original claims 8, 10, 46, and 47 and in the specification, for example, at page 26, line 32-page 27 line 2, and at page 47, lines 23-34.

Claims 8, 10, and 53 have been amended to recite, "comprising a hybridization medium of 50% (volume/volume) formamide with 0.1% bovine serum albumin/0.1% Ficoll/0.1% polyvinylpyrrolidone/50 mM sodium phosphate buffer at pH 6.5 with 5 x SSC at 42°C and washes at 42°C in 0.2 x SSC and 0.1% SDS, where the polypeptide [encoded by the complement of the sequence] has at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to B7RP1." Support for these amendments can be found in original claim 8, 10, and 53 and in the specification, for example, at page 25, lines 18-33.

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Claim 8 has been amended to remove references to SEQ ID NOs: 1 and 2, drawn to non-elected species. Claim 8 has also been amended to renumber the remaining subparts and to correct their dependencies. Support for amended claim 8 can be found in original claim 8 and in the specification, for example, at page 43, lines 12-22.

Claims 8 and 10 have been amended to correct the dependencies of the phrase "a nucleotide sequence complementary to any of". Support for amended claims 8 and 10 can be found in original claims 8 and 10 and in the specification, for example, at page 26, lines 23-26, and at page 62, lines 8-19.

Claim 49 has been amended to recite "a carboxy terminus at residue 302." Support for amended claim 49 can be found in original claim 49 and in the specification, for example, at Figure 12.

Claim 22 has been amended to delete an extra comma. Support for claim 22 may be found in original claim 22.

Applicants submit that the proposed amendments to claims 8, 10, 12, 19, 20, 22, 45-49, and 53-54 do not raise new issues and do not add new matter. The amendments also place the application in better condition for allowance or appeal. Thus, entry of the amendments is respectfully requested.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 8, 10, 12, 19-23, 43-49, and 52-54 under 35 U.S.C. § 112, second paragraph, for allegedly "failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Action at page 2. Applicants respectfully traverse this rejection. The Examiner discussed certain terms used in the claims which will be addressed in turn.

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A) "B7RP1"

The Examiner alleged that claims 8, 10, 12, 19-23, 43-49, and 52-54 are "indefinite in that they recite an arbitrary protein name, 'B7RP1'." Action at page 2. According to the Examiner, "B7RP1" can be distinctly claimed "by claiming a sufficient number of characteristics associated with the protein (e.g., activity and amino acid composition, etc.)" *Id.*

Applicants respectfully traverse. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, 12, 45-49, and 54 to recite "wherein the polypeptide [or polypeptide fragment] has at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1." Applicants assert that the specification teaches several sequences for each of CRP1 and B7RP1 and describes the structure of both proteins in detail at least at page 21, line 33, to page 23, line 21. Furthermore, the proposed claim amendments make clear what activity is associated with the "CRP1" or "B7RP1" proteins. Applicants therefore assert that claims 8, 10, 12, 19-23, 43-49, and 52-54 are not indefinite in their recitation of "B7RP1."

B) "At least one activity characteristic" of B7RP1

The Examiner rejected claims 8, 10, 12, 19-23, 43-49, and 52-54 as allegedly being "indefinite in their recitation of polypeptides and polypeptide fragments having 'at least one activity characteristic' of B7RP1." Action at page 3. The Examiner admitted that the specification discloses that "binding to a CRP1 polypeptide and the ability to stimulate T cell proliferation and/or activation are activities which are characteristic of a B7RP1 polypeptide." *Id.* However, the Examiner alleged that two disclosed B7RP1

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activities do not "establish the metes and bound [sic] of what constitutes an 'activity characteristic' of B7RP1." *Id.*

Applicants respectfully traverse this basis for the rejection. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, 12, 45-49, and 54 to recite "wherein the polypeptide [or polypeptide fragment] has at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1." Applicants assert that the this basis for the § 112, second paragraph, rejection is therefore moot.

C) "High stringency conditions"

The Examiner rejected claims 8, 10, 12, 54, and dependent claims as allegedly being indefinite in their recitation of "high stringency conditions." The Examiner admitted that the specification discloses "general parameters for calculating such conditions and examples of such conditions." Action at page 3. The Examiner maintained, however, that in the absence of a clear definition of the phrase, the exact conditions being claimed are unclear.

Applicants respectfully traverse this basis for the rejection. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, and 54 to include the language, "comprising a hybridization medium of 50% (volume/volume) formamide with 0.1% bovine serum albumin/0.1% Ficoll/0.1% polyvinylpyrrolidone/50 mM sodium phosphate buffer at pH 6.5 with 5 x SSC at 42°C and washes at 42°C in 0.2 x SSC and 0.1% SDS." Applicants are not aware of any recitation of "high stringency conditions" in claim 12. Applicants assert that this basis for the § 112, second paragraph, rejection is moot.

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Applicants respectfully request reconsideration and withdrawal of the § 112, second paragraph, rejection.

Rejections Under 35 U.S.C. § 112, first paragraph (written description)

The examiner rejected claims 8, 10, 12, 19-23, 43-49, and 53-54 under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." Action at page 3. Applicants respectfully traverse this rejection. The Examiner discussed certain terms used in the claims which will be addressed in turn.

A) "Variants"

The Examiner rejected certain claims that "recite a genus of polypeptides but do not require that the instant polypeptides share any testable functional activity, a feature deemed essential to the instant invention." Action at page 4. Specifically, the Examiner argued that "there does not appear to be an adequate written description in the specification as filed as to a *correlation* between the structures encompassed by 70% identity or variants of the recited sequence and any *particular* function." Action at page 4 (emphasis original). The Examiner further stated that, "[i]n the absence of a particular testable function and some structural basis for that function that must be maintained by members of the genus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention." Action at page 4.

Applicants respectfully traverse this rejection and incorporate by reference the arguments made at pages 13-14 of the Amendment and Response filed April 30, 2003.

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Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, and 46-47 to recite "at least about 95 percent identical," and also to recite "at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1."

Applicants assert that the specification describes the nucleotide and amino acid sequences of both murine and human B7RP1 at least at SEQ ID NOs: 6, 7, 11, 12, 16, and 17 (*see* Figures 2A and 3A). Polypeptides that are at least 95% identical to a polypeptide having a particular sequence identification number recited in the claims are specifically structurally related to such sequences. Moreover, the specification describes a T-cell proliferation assay at Example 17, an in vitro T-cell stimulation assay at Example 21, and a binding assay between a CRP1 and a B7RP1 protein at Example 8. Therefore, adequate structure and function is provided and the claimed invention is adequately described.

Thus, the Examiner has failed to establish Applicants' failure to comply with the written description requirement of § 112, first paragraph.

B) "Polypeptides Comprising Fragments"

The Examiner rejected certain claims alleging that "[f]ragment language that encompasses open (comprising) claim language permits unidentified flanking sequence to be added any [sic] subsequence of a particular SEQ ID NO and so does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." Action at page 5. The Examiner admitted that for such a claim to be allowable, it is not necessary that every possible flanking sequence be described, and that the "comprising" language in and of itself does not render such a claim unpatentable. *Id.* The Examiner's concern appears to be that the cited language

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encompasses a large genus of polypeptides and does not impose a correlation between the structure of the genus and a testable function. *Id.*

Applicants respectfully traverse this rejection and incorporate by reference the arguments made at page 14-15 of the Amendment and Response filed April 30, 2003. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, 45 and 47 which recite the language, "wherein the fragment has at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1." Applicants assert that the specification describes how to make a polypeptide containing a fragment of one of the polypeptide sequences of the invention (*see*, e.g., the B7RP1-Fc fusion protein construct described at page 31, lines 7-30, and Example 7). Moreover, the specification describes a T-cell proliferation assay at Example 17, an in vitro T-cell stimulation assay at Example 21, and a binding assay between CRP1 and B7RP1 at Example 8. Thus, adequate structure and function are provided by the specification and the claimed invention is adequately described.

Thus, the Examiner has failed to establish that there is insufficient written description for claims containing the language "polypeptides comprising fragments."

C) "A carboxy terminus at about residue 302"

The Examiner rejected claim 49 for its recitation of "at about residue 302." Action at pages 8-9. Applicants propose amending claim 49 to read "at residue 302," which renders the instant rejection moot.

Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph, rejection based on the written description requirement.

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Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner rejected claims 8, 10, 12, 19-23, 45-47 and 53-54 under 35 U.S.C. § 112, first paragraph, alleging that those claims were not reasonably enabled by the specification. See Action at page 6. The Examiner discussed certain terms used in the claims which will be addressed in turn.

A) "Variant polypeptides"

The Examiner alleged that "the experimentation left to those skilled in the art to determine which 'variant' sequences would still result in polypeptides having the same function as the human and mouse B7-RP1 polypeptides disclosed in the specification as filed is unnecessarily, and improperly, extensive and undue." Action at page 7. The Examiner stated that "the skilled artisan would not reasonably expect such 'variant' polypeptides to have the same function as the instantly recited SEQ ID NOs, particularly when the family of B7-like proteins was known to have variable function." *Id.* The Examiner further stated that in the "absence of guidance as to which amino acid residues provide a particular function, it is unpredictable which, if any, sequences having 70% identity would maintain that function." *Id.*

Applicants respectfully traverse this rejection and incorporate by reference the arguments made at pages 16-18 of the Amendment and Response filed April 30, 2003. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8 , 10, and 46-47 to recite "at least about 95 percent identical," and also to recite "at least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1."

Applicants submit that given the recitation of SEQ ID NOs: 7, 12, and 17 and the teachings of the specification, one skilled in the art would have been able to isolate and

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identify polypeptides having at least 95% identity to the polypeptides of SEQ ID NO: 7, 12, or 17 and which have one or more of a T-cell proliferation activity, a T-cell activating activity, and a binding activity to CRP1. Furthermore, as discussed previously, the specification explicitly teaches appropriate assays for use in determining such protein activities at least at Examples 8, 17, and 21. Applicants submit that the Examiner has failed to establish that claims 8, 10, and 46-47 are not fully enabled.

B) "Fragments Comprising"

The Examiner rejected claims that "recite in various forms polypeptides comprising 'fragments' of a certain number of amino acids residues of the various SEQ ID NOS (or encoding nucleic acids)." Action at page 8. The Examiner alleged that "before the skilled artisan can make polypeptides comprising "fragments" with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences." *Id.* Applicants respectfully traverse this basis for the rejection. The Examiner admitted that the specification provides guidance regarding certain B7RP1 fusion proteins, such as a fusion between the extracellular domain fragment of B7RP1 and the Fc region of IgG1. *Id.* However, the Examiner maintained that "the scope of the instant claims encompasses *any* fragment and *any* additional sequences" and the cited B7RP1 fusion protein is only "a single example limited to a particular fragment of B7RP1." *Id.* (emphasis original).

Applicants respectfully traverse and incorporate by reference the arguments made at page 18 of the Amendment and Response filed April 30, 2003. Solely to expedite prosecution and without acquiescing to any rejection, Applicants propose to amend claims 8, 10, 45, and 47 to include the language, "wherein the fragment has at

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least one activity selected from a T-cell proliferation activity, a T-cell activation activity, and a binding activity to CRP1."

Applicants assert that, in view of the specification, one skilled in the art would have been able to make the claimed fragments and to test them for the ability to stimulate T-cell proliferation, to stimulate T-cell activation, or to bind to CRP1 without undue experimentation. As detailed previously, the specification describes a T-cell proliferation assay at Example 17, an in vitro T-cell stimulation assay at Example 21, and a binding assay between a CRP1 and a B7RP1 protein at Example 8. Even should the fragment contain additional flanking sequences (such as the B7RP1-Fc fusion protein described in the specification at page 31, lines 7-30 and Example 7), testing the resulting fusion protein for one of the enumerated activities was well within the guidance of the specification and the level of skill in the art.

Thus, the Examiner has failed to establish that the claims reciting the language "fragments comprising" are not enabled by the specification.

Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph, rejection based on enablement.

Rejections Under 35 U.S.C. § 102(a)

The Examiner rejected claims 8, 10, 12, and 20 as allegedly "being anticipated by Ishikawa et al. (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999)." Action at page 9. The Examiner admitted that GenBank Accession No. AB014553 is not available as prior art. *Id.*, at page 10. The Examiner, however, stated that "the policy of GenBank has been that *if a paper citing* the sequence *or accession number* is published prior to a specified date, the sequence *will be released upon publication.*" *Id.* (emphasis original). The

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Examiner concluded, therefore, that "the disclosure of the GenBank accession number in Ishikawa et al. was sufficient to place the public in possession of the instantly claimed invention because even though the release date of Accession No. AB014553 was after the effective filing date of the instant claims, the policy of GenBank regarding sequence availability after publication permitted a public in possession of the Accession No. taught by Ishikawa et al. to obtain the sequence information." *Id.* The Examiner further indicated that the authors of Ishikawa would have provided the reaction conditions and PCR primers upon request. *Id.* The Examiner asserted that because the public could have demanded the sequences in Accession No. AB014553 prior to the relevant priority date, the instant invention is anticipated. *Id.* Applicants respectfully traverse this rejection and incorporate by reference the arguments at pages 20-21 of the Amendment and Response filed April 30, 2003.

According to the policy of GenBank stated on the Internet:

> [s]ome authors are concerned that the appearance of their data in GenBank prior to publication will compromise their work. GenBank will, upon request, withhold release of new submissions until a future date to allow for publication of the data. We encourage authors to inform us of the appearance of the published data; failure to do so could result in delays in making your data available in GenBank.

National Library of Medicine, Fact Sheet: Submitting Data to GenBank®," *at* http://www.nlm.nih.gov/pubs/ factsheets/sdgenbk.html (last modified Oct. 23, 2001) (copy enclosed). The Examiner has provided no evidence that the authors of Ishikawa did not, in fact, request that GenBank withhold their data from release to the public until a future date. In such a situation, GenBank explicitly requests that the authors inform GenBank of any publication, as stated in the previous passage. *Id.* A failure of the authors to do so "could result in delays in making [the] data available in GenBank." *Id.*

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This policy does not discuss whether any member of the public other than the authors may request release of the sequence data. *Id.* The Examiner has therefore provided no support for her contention that GenBank would have made Accession No. AB014553 available to a requesting member of the public any earlier than the actual publication date of this sequence in the GenBank database.

The Examiner alleged that even should the GenBank sequence not be available as prior art, the reaction conditions and PCR primers were available upon request from the authors of Ishikawa, thereby putting the public "in possession of a method of making the instantly claimed invention." Action at page 10. Applicants disagree. To anticipate, a reference must disclose every element of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Moreover, the reference must be enabling. *See* MPEP § 2121.01. The Examiner provides no support for her position that an author's intent to provide information can replace actual disclosure in a publication.

Accordingly, the Examiner has failed to establish that Ishikawa "put the public in possession of the claimed invention" at the time of the filing of the application. Therefore, the Examiner has failed to establish that Ishikawa is an enabling disclosure. In the absence of demonstrated evidence that GenBank Accession No. AB014553 was publicly available prior to February 3, 1999, the 102(a) rejection cannot stand.

Applicants respectfully request reconsideration and withdrawal of the § 102(a) rejection.

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Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 19-23 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ishikawa in view of Linsley. See Action at page 11. Each of those

claims include a polypeptide of claim 8, 10, or 12, which the Examiner rejected as allegedly being anticipated by Ishikawa. The Examiner cited Linsley as allegedly showing certain additional elements of the rejected claims.

For at least the reasons stated above, Ishikawa does not anticipate claim 8, 10, or 12. Because the polypeptide of claim 8, 10, or 12 is patentable over Ishikawa in view of Linsley, claims 19-23 are likewise patentable. Moreover, Applicants need not address the Examiner's contentions with respect to other elements of those claims. By not addressing those contentions, Applicants in no way acquiesce to those contentions.

Conclusion

Applicants respectfully request reconsideration and reexamination of the application, and the timely allowance of the pending claims. If the Examiner does not consider the application to be in condition for allowance, Applicants request that the Examiner call the undersigned ((650) 849-6620) to arrange an interview prior to taking action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 14, 2003

By: Jennifer L. Elliott 50,584
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